K011120
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NIPRO DIABETES SYSTEMS
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MAY - 8 2001

SUMMARY OF SAFETY AND EFFECTIVENESS
Glucopro™ Infusion Set

§807.92 (a)(1)

Contact Person: Kirk Ramey
Senior Vice President

Date of Summary Preparation: April 10, 2001

§807.92 (a)(2)

Trade Name: Glucopro™ Infusion Set

Common Name: Infusion set

Classification Name: Intravascular administration set (21 CFR §880.5440)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: Tender infusion set, Nipro Safelet Cath

§807.92 (a)(4)

Description of Device: The Glucopro infusion sets are connected to a medication reservoir proximally (i.e., a syringe that is placed within an infusion pump, such as an insulin pump) and distally inserted into the subcutaneous tissue of the user. The infusion set attaches to the medication reservoir by means of a female luer connector and is inserted into the patient through an introduction cannula. The 26 gauge indwelling catheter is connected to tubing of various lengths. The materials used for the components include:

PVC/polyethylene; polyvinyl chloride; polytetrafluorethylene; stainless steel; polycarbonate; polypropylene; and, trace amounts of silicone as a lubricant. All of these materials are typically used in medical devices.

§807.92 (a)(5)

Intended Use:

The Glucopro infusion set is an administration infusion set intended to be used for subcutaneous infusion of medicine solutions, such as insulin, from an external infusion pump.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The Glucopro infusion set is similar to legally marketed devices with the same intended use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

Nipro Diabetes Systems, Incorporated
C/O Ms. Kaelyn B. Hadley
Consultant
C. L. McIntosh and Associate Incorporated
1384 Copperfield Court
Lexington, Kentucky 40514

Re: K011120
Trade/Device Name: Glucopro Infusion Set
Regulation Number: 880.5440
Regulatory Class: II
Product Code: FPA
Dated: April 2, 2001
Received: April 12, 2001

Dear Ms. Hadley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) number (if known): K_____

Device name: Glucopro Infusion Set

Common Name: Infusion Set

Classification Name: Intravascular administration set

Product code: FPA

Classification: 880.5440, Class II

Indications for use: The Glucopro infusion set is an administration infusion set intended to be used for subcutaneous infusion of medicine solutions, such as insulin, from an external infusion pump.

(Please do not write below this line- continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The- Counter-Use___ (optional Format 1-2-9)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K071120